Chemical Industry Presses EPA To Seek OMB Review Of New IRIS Handbook

Posted: July 8, 2013

The American Chemistry Council (ACC) is pressing EPA to submit its new handbook for how it performs its Integrated Risk Information System (IRIS) chemical assessments to the scrutiny of the White House Office of Management and Budget (OMB) before finalizing it.

The agency document, "Materials Submitted to the National Research Council [NRC] Part I: Status of Implementation of Recommendations," was released publicly last January after IRIS managers submitted it to the NRC committee that is reviewing the influential program.

The submission to NRC outlines changes IRIS staff has already implemented in attempts to respond to criticisms in the NRC's 2011 review of the draft formaldehyde IRIS assessment, as well as improvements that are "in progress" at the program, such as changes to the scoping process for upcoming reviews (*Risk Policy Report*, Feb. 12).

The agency indicated that it would welcome public comments on the document, but did not set up an electronic docket to collect them, or issue a *Federal Register* notice announcing a comment period. Both actions are additional requests that ACC makes of EPA in the extensive comments that it sent EPA and the NRC committee June 25.

ACC argues that the EPA should submit the handbook to OMB for review before finalizing it, arguing that the handbook is a policy document and represents economically significant policy.

ACC says that "the IRIS handbook and associated documents should be treated as economically significant guidance documents subject to the requirements of the OMB Final Bulletin for Agency Good Guidance Practices and subject to review by the [OMB] Office of Information and Regulatory Affairs under Executive Orders 12866 and 13563," the comments say. *The comments are available on InsideEPA.com.* (*Doc ID: 2439263*)

The comments includes many of ACC's longstanding wish list items for the IRIS program: EPA should expedite its response to recommendations from the National Academy of Sciences (NAS) panel that reviewed EPA's draft IRIS assessment of formaldehyde in 2011; that all IRIS assessments should include uncertainty and sensitivity analyses, including providing ranges of risk estimates rather than point estimates; that EPA adopt a weight of evidence framework for reviewing relevant studies and determining which are relied upon in the assessment and provide stakeholders greater access to EPA's planning and scoping of new assessments.

Some of the recommendations seem to place ACC in the position of pressing EPA to quickly make policy decisions -- before the ongoing NAS IRIS panel completes its work and issues its report -- while in other instances, such as specific IRIS assessments, the industry association often presses for deliberation and consistent policy application.

"We think they could be doing a better job on assessments in the pipeline. The could identify the criteria they're using and use a weight of evidence framework now," ACC's Nancy Beck said during a June 26 call with reporters. "They don't need to wait for [NRC] . . . EPA could be doing a much better job while it's waiting for [NRC]."

Beck referenced remarks last fall from Kenneth Olden, director of EPA's National Center for Environmental Assessment, which manages IRIS, who said that he can and will make improvements to the program while awaiting the NRC panel's report.

Beck added that changes EPA makes to the IRIS program in the interim "may not be perfect, they may not be consistent . . . but we need to be seeing some progress. I hope we don't have to wait for the NAS report to see progress in some areas."

Beck's colleague, Kimberly Wise, raised similar arguments with Vincent Cogliano, the acting director of the IRIS program, during a July 2012 public listening session for the draft IRIS assessment of ammonia. Cogliano and Wise jousted over when and how much change EPA should embark upon in the IRIS program, particularly regarding a weight of evidence tool, prior to receiving the NRC recommendations.

Cogliano reminded Wise that he and colleagues are implementing the 2011 NRC recommendations, but doing so will be a gradual, multi-year process -- as NRC acknowledged in its report. Cogliano questioned what changes ACC representatives would like IRIS staff to make before NRC completes its broader review of the program.

Wise replied, "There are some general guidelines out there. Put forward [a recommendation] for peer review. Ask the stakeholders to review [it] and suggest recommendations. We don't want to see you wait for two years, but there needs to be public involvement" (*Risk Policy Report*, Aug. 14).

IRIS managers are also dealing with concerns expressed by the NRC IRIS review panel chairman, Jonathan Samet, regarding the challenges of trying to review an evolving program. During the committee's meeting last December in California, Samet professor at the University of Southern California's medical school, called the IRIS program a "moving target." He said that because the NRC committee is tasked with providing comments on "where you are going . . . we are going to have to make sure we know where you're going, and so you need to know where you're going" with changes to the IRIS process (*Risk Policy Report*, Feb. 12). -- *Maria Hegstad*

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Risk Policy Report - 07/09/2013, Vol. 20, No. 28

Environmentalists Criticize EPA For Enhancing Industry Role In IRIS Reviews

Posted: June 24, 2014

Environmental and public health groups are criticizing EPA for selecting more industry speakers than others at recent and upcoming public meetings to discuss pending Integrated Risk Information System (IRIS) chemical assessments, charging the selection will enhance industry influence on the assessments.

"We are deeply concerned by the imbalance in participation for the June 2014 Bimonthly Public Science meeting," the Environmental Defense Fund (EDF) writes in June 11 comments submitted to EPA ahead of a June 25-27 meeting.

"This serious problem stems from differences in both incentive structures and resources among stakeholders. While parties with clear financial interests in the outcome of these assessments are motivated and able to spend time and money on these meetings, scientific experts without such financial interests are not," the group says. *Relevant documents are available on InsideEPA.com. (Doc. ID: 2474126)*

"Achieving balance involves more than just improving accessibility; it also requires ensuring that actual participation is balanced, through placing speaking limits on overrepresented stakeholders and undertaking explicit outreach and providing support to underrepresented stakeholders," the letter says.

The group points to recommendations from the National Academy of Sciences' National Research Council (NRC) in its recent review of the IRIS program, which recommends that EPA model a program similar to its Superfund office's technical assistance for community groups. These resources allow communities to provide informed comments on cleanup decision making.

The comments reiterate concerns that Richard Denison, an EDF senior scientist, outlined in 2012, where he advocated for reducing the number of public meetings that EPA holds on IRIS assessments, arguing that more public meetings led to greater imbalance in the input that EPA receives, since industry representatives have the resources to attend multiple meetings, while academic and non-profit groups often do not. He charged that the additional public processes take too long and delay public health interventions.

EPA has been seeking to increase the number of public meetings and consultations it holds as it develops new IRIS assessments, providing chemical managers an opportunity to outline preliminary materials and drafts of IRIS assessments for public comments and discussion of scientific issues. Attendees at the meetings tend to be representatives of industry, such as the Small Business Administration, or regulated entities,.

The next IRIS meeting, scheduled for June 25-27, is slated to discuss the pending assessments of inorganic arsenic and hexavalent chromium, two chemicals with long-running assessments that have spanned multiple years, peer reviews and other turns. In response to suggestions at the first two bimonthly meetings, the discussions have been divided along scientific topics relevant to each assessment, and discussants for each topic selected.

The agenda for the meeting lays out eight scientific topics related to arsenic, and 14 unique speakers on those topics. Of those, 10 are industry representatives or industry contractors. Similarly, for hexavalent chromium, there are six topics with a dozen unique speakers. Of these, 11 are industry representatives.

An EDF scientist represents the only NGO on EPA's agenda discussing arsenic.

EDF and others are concerned about the imbalance in the speakers at the bimonthly IRIS meetings. Kathleen Burns, director of Sciencecorps, has also expressed her dismay over the industry representation to IRIS management. "If they had reached out to the [non-governmental organizations (NGOs)] who commented [on the arsenic IRIS assessment plans] in 2013, they would have had a very robust response," Burns says.

An EPA spokeswoman says, "We recognize that obtaining different perspectives on scientific issues is important, and for that reason we have been exploring new mechanisms to reach out to scientists who might be interested in agenda topics to invite them to participate in our meetings."

She adds that agency staff "also recognize that not all of our stakeholders have the resources to travel . . . For the past year and a half, every public meeting held by the IRIS Program has also been available by webinar. This has been a successful model in that we often have 50-100 individuals participating from outside of Washington, DC, by webinar. We are working to better ensure that webinar participants can more fully engage in our meetings, including introducing telephone connections that allow webinar participants to actively participate in discussions."

With regard to the June public meeting, the spokeswoman said that the agenda "reflects all of the individuals who requested to participate in the scientific discussions. We know that there are other perspectives out there. Accordingly, we welcome ideas from the public about how to obtain different perspectives on complex scientific issues that are discussed at IRIS bimonthly public science meetings."

An ACC spokesman said that "with EPA opening up access to participation, they're trying to open up that dialogue. As far as some of those recommendations, it would be up to EPA to determine whether they would do those things."

EDF also raises concerns about some of the scientific issues included on the agendas of both past and the upcoming IRIS meetings, urging EPA to limit comments received specifically to the chemicals under discussion, or to elevate the meetings to discuss general science issues and encourage broader participation.

For example, during the April meeting focused on the agency's ongoing assessment of the flame retardant hexabromocyclododecane (HBCD), EPA asked what changes in thyroid hormones the agency should consider significant. But this issue is relevant to other chemicals, such as the rocket fuel ingredient perchlorate, and should be discussed in a broader setting, EDF says. -- *Maria Hegstad*

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Environmental Policy Alert - 06/25/2014, Vol. 31, No. 13

NAS Advice Opens Door To New EPA Debate Over Controversial Risk Ranges

Posted: June 6, 2014

EPA officials are preparing to discuss how they might address recent National Academy of Sciences (NAS) advice to improve the influential Integrated Risk Information System (IRIS) program, including consideration of the use of controversial risk ranges, rather than single point estimates, as a way to account for scientific uncertainties.

But the agency's consideration of the advice could be controversial -- just as it was when EPA's Bush-era research chief George Gray pushed the approach -- because some staff fear that quantifying uncertainty is resource intensive while adopting risk ranges will undercut protective risk management standards and create difficulties for regulators that rely on the single point risk estimates to justify their decisions.

The idea of presenting uncertainty around the single point estimate risk values contained in IRIS documents remains a long-standing sore point for some, who argue that such numbers do not reflect the reality of uncertainties and variabilities inherent in assessing the toxicity of environmental contaminants, often with limited data.

NAS' May 6 report, "Review of EPA's [IRIS] Process," is the latest from the academy to recommend that the IRIS program should address this uncertainty in its assessments, in part by including a range of risk estimates rather than a single point estimate.

During a May 5 conference call with reporters, Jonathan Samet, the NAS committee chairman, said that the committee, echoing recommendations in earlier NAS reports, recommends that "rather than bring forward a single number" IRIS assessments should include two dose-response values, "the traditional lower-bound estimate, and to show the range, provide a central estimate as well."

The report explains that "[r]eporting both values provides information on statistical uncertainty, such as sampling variation, and makes available to the risk assessor the full range of information."

Samet noted that EPA's draft IRIS handbook -- an effort started in response to NAS' critical 2011 review of the draft IRIS assessment of formaldehyde -- is incomplete. It does not yet contain a quantitative chapter discussing how IRIS assessors should calculate the toxicity values in the assessments. "That is the one missing piece of the draft handbook," he said. "We hope these recommendations will be helpful to them as they write" it.

The report also recommends that EPA seek peer review of the draft handbook, when completed.

NAS' latest recommendations on increasing the use of uncertainty analysis echoes similar calls in earlier NAS reports, such as the 2011 formaldehyde report, the 2009 "Science and Decisions: Advancing Risk Assessment" and a 2013 report from NAS' sister academy, the Institute of Medicine, "Environmental Decision-making in the Face of Uncertainty."

Ken Olden, director of EPA's National Center for Environmental Assessment, who leads the IRIS program, told members of a Science Advisory Board peer review panel during a May 22 conference call that the agency is planning to hold a public workshop next October to "focus on the recommendations made" in the latest NAS report. He said he is inviting members of the committee that wrote the report to participate in the workshop, and chair some of its individual sessions.

The upcoming workshop could provide a venue for the debate over risk ranges, much as it did during the Bush administration.

As President George W. Bush's last research chief, Gray argued the approach is more scientifically rigorous. He pressed for detailed uncertainty analysis and other cancer modeling changes to be conducted in one of several controversial assessments underway in the IRIS program at that time, including the assessment of the drycleaning solvent tetrachloroethylene (perc).

His efforts delayed release of the document by two years, and Gray left office before the assessment was completed in 2012 -- without the comprehensive uncertainty analysis he had sought. NAS in its latest report on IRIS cited the perc IRIS assessment

as an example of what it considered uncertainty analyses "conducted for select individual intermediate stages in the process (such as dose-response modeling and low-dose extrapolation), often in isolation from one another." The report acknowledges that such uncertainty analyses "have become more common in IRIS assessments."

But EPA sources, environmentalists and others expressed misgivings about the approach. Using ranges instead of single point estimates in IRIS "will mean that providing consistency across decisions, programs, sites and standards will be an enormous challenge," one EPA staffer said at the time.

For example, the source warned it could create avenues for softening EPA safety standards for toxics. "This will make it harder for EPA regulators to draw a consistent line in the sand about acceptable exposures" at cleanup sites and when addressing other public health threats.

But long-time proponents of uncertainty analysis have been renewing their calls for EPA to expand its adoption, even before issuance of the latest NAS report.

For example, Sen. David Vitter (R-LA), the ranking Republican on the Senate environment committee, asked Thomas Burke, President Obama's nominee to serve as EPA research chief, whether he would commit to following White House guidance documents that require disclosure of uncertainties.

In written questions to Burke following his December 2013 confirmation hearing, Vitter notes that the Office of Management & Budget (OMB)'s Circular A-4 guidance "requires key uncertainties to be disclosed and quantified to the extent possible to inform decision makers and the public about the effects and uncertainties of alternative regulatory decisions. However, EPA has a practice of excluding and failing to quantify key uncertainties in the cost-benefit analysis of rulemakings."

He asked Burke generally if he would commit to following all OMB circulars and guidance and asked specifically "How will you ensure that key uncertainties are included and quantified in the cost-benefit analysis of EPA rulemakings?"

Burke replied Jan. 17 that while not familiar with the "specific requirements" of Circular A-4 guidance, if confirmed he would "commit to follow all applicable OMB circulars and guidelines and to support the broader agency's efforts to comply with any such requirements."

But consideration of the approach is already prompting concerns from some agency sources, who suggest that one of the pressures against producing IRIS ranges instead of a single number may be regional and program offices that use the IRIS documents to set clean up standards and make other decisions.

"It's easier, if I have a number, versus a range," to make those decisions, one agency source says, adding that a range "puts the responsibility someplace else. We all would like a number." The source said that IRIS leadership would need input and buy-in from leaders in other agency program offices before such an approach could be adopted. A range, the source says, "puts a little more pressure on the folks" in the program offices.

A second agency source also noted the problems a risk range presents for program offices and their risk managers, asking rhetorically, when presented with a range for a cleanup level, "What community is going to be happy with the high" end of the range?

The first source, however, says that IRIS leaders should consider the recommendation, adding that risk ranges will make the jobs of IRIS assessors "easier and more accurate" because they "don't know if it's this number or that number. It would be better to communicate a range."

The issue is not unique to IRIS. During discussions of how to present risk estimates from IRIS and other regulatory agencies to decision makers at the May 21 Alliance for Risk Assessment Beyond "Science and Decisions" conference, a Texas Commission on Environmental Quality (TCEQ) toxicologist was asked about his interaction with TCEQ risk managers. "Usually they just ask, 'What's the number?' said Mike Honeycutt, a TCEQ toxicologist and risk assessor. "Some do like to get into the details." -- *Maria Hegstad*

EPA Nominee Declines Vitter's Call For Second Formaldehyde Risk Review

Posted: May 27, 2014

Thomas Burke, President Obama's nominee to serve as EPA's research chief, is, for now, declining a request from Sen. David Vitter (R-LA) to send EPA's next draft risk assessment of formaldehyde to the National Academy of Sciences (NAS) for peer review, saying such a commitment is premature.

"While I can assure there will be rigorous peer review of the revised formaldehyde document, I believe it is premature for me to provide assurance that another NAS committee be convened specifically to re-review formaldehyde." Burke told Vitter in a recently obtained written response to questions following his confirmation hearing late last year. *Relevant documents are available on InsideEPA.com. (Doc. ID: 2471295)*

Vitter's spokesman did not respond to a request for comment. Vitter's question signals a renewed effort by the lawmaker to seek an NAS review of any revised formaldehyde assessment EPA may develop.

It was Vitter, in 2009, who forced EPA to seek NAS review of an earlier formaldehyde assessment by blocking confirmation for Paul Anastas, Burke's predecessor.

Vitter insisted that the agency seek NAS review of its draft assessment that proposed that exposure to the substance could cause certain forms of leukemia, and calculated a risk estimate based on that endpoint. But the resulting NAS review, published in 2011, provided a scathing critique of the agency's draft assessment as well as its broader Integrated Risk Information System (IRIS) program, prompting a series of reforms and an overhaul of the formaldehyde assessment.

"The NAS report on formaldehyde was critical of the process as well as the underlying science that EPA used in its draft assessment," according to Vitter's questions for Burke which were obtained through a Freedom of Information Act request.

"Given the significance of this risk assessment to the scientific process and for restoring the public confidence in EPA's science, it is imperative that you commit to having the NAS [relook] at the next iteration of the formaldehyde IRIS assessment. Can I have your assurance that this peer review will take place?" Vitter asked.

But Burke said he was not willing at that time to commit to such a review, though he did not rule it out in the future. "If confirmed, I will work to implement the recommendations of the NAS Formaldehyde Committee, not only for formaldehyde, but for all IRIS documents."

As a result of Senate rule changes, Vitter no longer has the power to block executive branch nominees though Burke and several other EPA nominees are still awaiting confirmation.

While the NAS recently released a new report favorably reviewing the progress EPA has made in reforming the IRIS program, Vitter remains critical of the program and EPA science in general.

"Overall, the changes that EPA has proposed shows some initial improvements in their chemical assessment process, but by no means is this report a reason to spike the football," Vitter said in a May 6 statement on NAS' review of the IRIS program.

"Chemical safety is a top priority, and we need to ensure that the EPA's basic goals are to develop assessments that provide an evidence-based foundation for ensuring that chemical hazards are assessed and managed well. If the EPA actually implements the National Academies suggestions, the process will slowly move to becoming much more effective and credible but this is just a first step and they have a long way to go."

While Vitter offered EPA faint praise in his response to the new NAS report, his questions for Burke suggest a series of fixes he would like to see the agency make to the IRIS program, as well as other EPA risk assessment practices -- though in several cases the nominee appears to reject the GOP senator's questions.

For example, Vitter echoes industry calls for EPA to "reality check" formaldehyde and other risk assessments to ensure they do not result in regulatory levels that fall below naturally occurring levels of the substances that are also produced industrially.

But Burke says EPA should continue to assess substances' hazards regardless of exposure levels and then consider how to deal with naturally occurring levels during the risk management phase.

Should IRIS assessments pass a reality check and "accommodate levels associated with existing natural exposures that are not known to be associated with any adverse effects at these low exposure levels," Vitter asks.

But Burke responded that "[t]he adverse effects of hazardous agents are not driven by whether or not they are 'naturally' occurring."

He added that "[n]atural occurrence and background levels are more appropriately considered in the risk management strategy."

Vitter also presses Burke regarding the idea of reality checking IRIS assessments using empirical data. "EPA's use of assumptions that it claims are 'public health protective' which err on the side of overstating risk when data are lacking . . . What are your views on the use of empirical data as a 'reality check' on overly conservative risk assessments, particularly those resulting from modeled or extrapolated data?"

Burke replied that "I believe that the fundamental mission of EPA is to protect public health, and therefore agree with approaches that are 'public health protective.' I also believe that the fundamental challenge in assessing risks is a lack of data. Therefore, it is not really valid to say that the EPA assumptions 'overstate the risks when data are lacking.' . . . In the absence of data, safety factors provide a time tested public health strategy to safeguard communities. I agree that more specific evidenced based approaches to safety factors and the protection of vulnerable subpopulations are needed. Also, risk characterization should include presentation of multiple modeling approaches to assist decision making and provide a 'reality check' based on empirical data."-- *Maria Hegstad*

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Chemical Industry Unveils Risk Analysis Principles Ahead Of NAS Reports

Posted: May 2, 2014

The American Chemistry Council (ACC) has released its "principles to enhance chemical hazard and risk assessments," to detail its positions in advance of a National Academy of Sciences (NAS) review of EPA's Integrated Risk Information System (IRIS) program, as well as a suite of other NAS reports on other key federal risk assessment issues.

ACC's new principles highlight four areas where the chemical industry association seeks improvement in federal risk assessment practices: assessment design, collection of data and methods for performing the assessments, communication of assessment findings and expert review of the assessments. *Relevant documents are available on InsideEPA.com. (Doc. ID: 2468761)*

"We believe our Principles along with the results of the pending NAS reviews will set the necessary benchmarks for ensuring these programs become a more useful decision-making tool for regulators," ACC President Cal Dooley said in a statement.

And Rick Becker, an ACC senior toxicologist, told reporters on a conference call that the industry group expects the NAS report "will add momentum to our calls for improving hazard and risk assessment."

The trade association unveiled its principles just days before the NAS is slated to release its long-awaited report on EPA's IRIS program, the agency's premiere chemical hazard assessment program. Due to their influence in EPA decision making, as well as that of state, local and even international agencies, draft IRIS assessments are closely watched by stakeholders, particularly when an assessment might lead to expensive cleanup or pollution control costs.

But the program has long been targeted by regulated industry for being overly conservative, especially after a 2011 NAS report strongly criticized EPA's draft assessment of formaldehyde.

The upcoming NAS report stems from language that Republicans attached to EPA's 2012 budget in response to the formaldehyde report, requiring NAS reviews of EPA's draft IRIS assessment of arsenic and as many as two other assessments.

NAS has released its recommendations for how EPA should perform the arsenic assessment. In lieu of reviewing other individual assessments, NAS conducted a broader review of the IRIS program.

The NAS' IRIS report is scheduled to be released May 6, an industry consultant said at the IRIS program's bimonthly meeting April 23.

In addition to the report on the IRIS program, other NAS panels are reviewing an EPA white paper on whether or how the agency should revise its chemical testing program to account for developmental risks at low doses of exposure. And NAS is also reviewing controversial assessments issued by the National Toxicology Program (NTP) on styrene and formaldehyde. Like EPA's draft formaldehyde assessment, NTP's assessment also found significant cancer risks from exposure.

The NAS report on IRIS is widely expected to be a linchpin in the agency's efforts to overhaul the program. Efforts underway by Ken Olden, EPA's director of the National Center for Environmental Assessment, have already seen revisions to the IRIS procedure and efforts to make the program more efficient. The agency has also created a new standing subcommittee of its Science Advisory Board to peer review the IRIS assessments.

ACC's principles also mark the latest effort by IRIS stakeholders to seek additional reforms of the program, as well as other federal risk assessment programs. For example, the group has long pressed EPA to clarify how IRIS chemical managers perform their weight of evidence analyses of toxicity information, and ACC sources are hoping that such recommendations are in the pending NAS report.

During a handful of public meetings, the NAS committee appeared to focus largely on the question of how IRIS chemical managers perform their weight of evidence analyses of toxicity information.

Dooley said that the principles are also intended to advance recommendations included in the NAS' 2011 review of EPA's draft IRIS assessment of formaldehyde, which reiterated long-standing concerns with the program and called for a series of revisions.

He said the principles are "to ensure can we take some of the proposals that were advanced . . . by NAS and take those to the next level and deploy those among the agencies that are involved in risk assessment."

Dooley added that the efforts to improve regulatory risk assessment and the principles are "a very high priority for ACC. . . . It's very complementary with what we hope will be the successful modernization of the Toxic Substances Control Act [TSCA]," Dooley said during an April 25 call with reporters.

Dooley later clarified that the primary audience of the principles is not intended to be those in Congress seeking to reform TSCA, the federal statute that oversees the management of industrial chemicals, but rather assessors and managers at IRIS and federal assessment programs.

With regard to design, the principles urge regulatory agencies to focus on the purpose, scope and approach for the assessment, and to avoid the use of default assumptions when data is available. In its data and methods section, ACC recommends established criteria to select studies for inclusion in assessments and calls for rigorous weight of evidence evaluation of data. The communication principles seek transparency from regulatory agencies, and press for central estimates and ranges of risk rather than single point estimates. Lastly, the principles call for "enhanced" peer review processes and accountability for agencies responding to reviewers' recommendations. -- *Maria Hegstad*

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Water Policy Report - 05/05/2014, Vol. 23, No. 9

Rejecting Industry Calls, EPA Continues To Advance ETBE Risk Assessment

Posted: April 28, 2014

EPA's influential Integrated Risk Information System (IRIS) program is planning to complete its assessment of the human health risks of the little-used fuel oxygenate ethyl tert-butyl alcohol (ETBE), despite industry calls to shelve the analysis and focus on higher priority substances that are marketed for use in the United States.

Ken Olden, director of EPA's National Center for Environmental Assessment (NCEA), who heads the IRIS program, told an IRIS bimonthly stakeholder meeting April 23 that staff will complete the ETBE assessment. "We went back and we checked, and there is a request, there is a need for ETBE [to be assessed]. And we're continuing with the assessment," Olden said.

His announcement follows a series of calls from industry officials urging EPA to drop its assessment. The Japanese Petroleum Industry Technology and Research Institute, Inc. (PITRI), whose officials met with EPA earlier this year, said in a letter prior to the meeting that it has "serious concerns with the [EPA] decision to proceed with an [IRIS] assessment of [ETBE]."

The letter, written by PITRI's attorney, Lynn Bergeson, says that EPA should "re-evaluate its apparent decision to move forward with this assessment and [we] believe . . . that ETBE should never have been determined to meet the criteria for assessment." *The letter is available on InsideEPA.com. (Doc. ID: 2468947)*

"Given all the many priority assessments EPA is challenged to complete, we urge EPA to focus on substances of a higher priority and not direct its limited resources to a substance that is neither marketed in the United States nor for which there is need for an IRIS assessment."

And at the last bimonthly IRIS stakeholder meeting in December, domestic fuel interests questioned Olden publicly about the relevance of producing an IRIS assessment for ETBE. Representatives of the American Petroleum Institute (API) and others questioned why ETBE was selected for assessment in the IRIS program. They noted that EPA has never certified the substance for use as an oxygenate after concerns over leaks of a similar chemical, methyl tert-butyl ether (MTBE), which the agency is already assessing.

Like PITRI, they also argued that IRIS resources would be better spent elsewhere, saying the chemical was not used in the U.S. as an oxygenate, and has no other known uses.

After the industry remarks, Olden raised the possibility that the assessment, a decade in the making, would be scuttled. Olden questioned staff about why the assessment remained on the IRIS to-do list if it was not in use in the country, and assured meeting attendees that he would investigate the matter (*Risk Policy Report*, Dec. 17).

But Olden told the April 23 meeting that while he "heard what was said at [the December] meeting . . . the information was not correct." He said the program assessed the relevancy of completing the assessment and found it is still needed.

Sources say that one EPA program office has a priority on the assessment and two other programs are also interested in the assessment. Vincent Cogliano, the director of IRIS, told the December meeting that EPA's air office originally requested the assessment some years ago, when ETBE was under consideration to be included in the gasoline oxygenators program.

Although EPA never approved the substance for use as an oxygenate, occurrence data indicates that the substance is appearing in ground water and soil, suggesting that EPA's water and waste offices may also be seeking the assessment.

IRIS produces the agency's "gold standard" assessments that are often closely watched by regulated entities because they can form the basis for agency regulations and other decision making. They are often also lengthy procedures, with some taking a decade or more to complete. At the same time, the program has fallen well short of producing the number of assessments annually that officials have sought.

To address the concerns, the program's managers have sought to prioritize and reduce the number of ongoing assessments that staff is handling in order to increase the program's efficiency and output, and meet goals for completing the reviews.

Olden, for example, has said he intends to reduce the number of assessments underway and has also sought internal review of all assessments, including asking EPA program office staff why assessments were nominated and whether they are still needed. Many assessments were delayed or removed from the schedule in order to hasten those considered most important.

The ETBE assessment, already underway since 2004, has also been mired in controversy. It was one of five IRIS assessments that former research chief Paul Anastas stalled or reviewed in 2010 because they referenced data from the controversial Italian laboratory known as the Ramazzini Institute. Industry and other critics argued that the Ramazzini labs' unorthodox methods overestimated the chemicals' cancer risks, and that as a result, EPA should not base its toxicity estimates upon its data.

In its Jan. 21 letter to EPA, PITRI's Bergeson argues that ETBE does not meet the agency's criteria for undertaking a resource-intensive IRIS assessment. Those criteria include potential public health impact; EPA statutory, regulatory, or program-specific implementation needs; availability of new scientific information or methodology that might significantly change the current IRIS information; interest to other governmental agencies or the public; and availability of other scientific assessment documents that could serve as a basis for an IRIS assessment.

Further, she notes that the decision to assess any given chemical substance depends on available resources, adding that the availability of risk assessment guidance, guidelines, and science policy decisions may also have an impact on the timing of EPA's decision to assess a chemical substance.

"PITRI appreciates EPA's limited resources to conduct IRIS assessments and the need, considering those resources, to select substances for assessment that are particularly relevant to EPA or other agencies for the protection of public health through regulatory means. ETBE does not meet these criteria and thus should be dropped from the IRIS program," Bergeson says.

Among other things, she argues that there is no public health or regulatory need for an ETBE assessment, noting that the agency declined to include the substance in its 2009 list of contaminants the agency may want to consider for regulation under the Safe Drinking Water Act.

Further, a 2006 U.S. Geological Survey (USGS) report noted that ETBE was detected "infrequently" in sampled domestic and public drinking water wells, with a detection frequency well below 1 percent at an assessment level of 0.02 micrograms per liter (ug/L), the letter says.

But the chemical does appear -- though generally at levels less than 0.2 ug/L of water -- in USGS groundwater monitoring. USGS' National Water-Quality Assessment Program in 2006 published "Volatile Organic Compounds in the Nation's Ground Water and Drinking-Water Supply Wells," which includes sampling of ETBE in aquifers and wells that provide water to public water systems. In 1,683 aquifer samples, USGS detected ETBE in 0.18 percent of the samples. Similarly, in public wells, of 818 samples, USGS detected ETBE in 0.14 percent.

Additionally, while the chemical may not appear to be a priority from the USGS data, it may pose a hotspot problem. For example, well sampling data from Jacksonville, MD, indicates that wells tested in that area between 2006 and 2010 had widely varying levels of ETBE, some as high as in the thousands of ug/L. The testing was performed following the release of some 26,000 gallons of gasoline from a nearby ExxonMobil gas station in 2006. The data, collected by multiple interested parties including the Maryland Department of the Environment, appear to show that those levels tended to drop dramatically over the testing time span. Numerous other chemicals, often MTBE, accompanied the presence of ETBE in the data.

And California's GeoTracker database, which contains groundwater and soil sampling data at cleanup sites around the Golden State, also indicates a wide variety of levels of ETBE at nearly 600 sites where the chemical was detected in the past three years. GeoTracker shows that the levels of ETBE detected range from 0.97 ug/L at an Arco marine terminal in Long Beach to 4,000 ug/L at a Chevron leaking underground storage tank in Los Angeles.

Of these, more than four-fifths of the sites were less than 10 ug/L. As in the Jacksonville, MD data, GeoTracker shows that ETBE is generally detected along with other chemicals, often including MTBE. -- *Maria Hegstad*

Faulting Data, W.R. Grace Urges EPA To Drop Libby Asbestos Risk Study

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Attorneys for bankrupt mining company W.R. Grace have filed a Data Quality Act (DQA) petition urging EPA to drop its precedent-setting effort to assess the risks posed by Libby amphibole asbestos (LAA), saying the agency's draft analysis set a noncancer risk value that is so strict it would force cleanup below naturally occurring levels.

The company filed a Feb. 26 petition charging that the agency's draft Integrated Risk Information System (IRIS) assessment uses an inappropriate nonadverse health endpoint for its noncancer risk values and violated a number of quality standards set by the DQA. *Relevant documents are available on InsideEPA.com. (Doc. ID: 2463778)*

"Given the pervasive nature of these deficiencies that call into question the scientific validity of the Draft Assessment, and the likely significant impact on public and private resources if the Draft Assessment continues to be disseminated in this or a similar form, we request that the Draft Assessment be removed from the Agency's IRIS website and not be further disseminated or used in its current or a revised form until the fundamental shortcomings identified herein have been corrected," the petition says.

The petition could give the company a means of challenging any regulatory decisions the agency makes based on the assessment, though no court has ever ruled that such petitions are judicially reviewable or enforceable.

But the agency is not likely to drop the assessment, especially given pressure from Montana lawmakers for the agency to quickly complete it. And an agency source said recently that officials are planning to complete the assessment later this summer -- even before publication of a workplace study that industry and GOP lawmakers have urged the agency to consider.

EPA's science advisors have largely backed the endpoint that the agency selected.

Grace operated a vermiculite mine in the small town of Libby, MT, for decades, beginning in the 1960s, but the vermiculite was contaminated with a particular type of asbestos, LAA. Grace ceased mining operations in Libby in 1990, and the area became a Superfund site in 2002. Since a series of news reports publicized respiratory illnesses in workers exposed to LAA in 1999, Grace filed for Chapter 11 bankruptcy in 2001, according to an EPA summary of its 2007 settlement with the company. The agency announced last month that Grace paid EPA more than $54 million "to resolve environmental liability claims pursuant to the company's bankruptcy plan of reorganization" regarding cleanup liabilities at 39 Superfund sites in 21 states.

That does not include Libby, which EPA and Grace settled in 2008. "Grace paid EPA $250 million to cash out its liability for the Libby site with the exception of the Libby Mine and contamination migrating from the mine," according to EPA's site.

EPA has since 2007 sought to assess the contaminant's risks as part of its influential IRIS program. Once finalized, the risk values in the assessment will be used as the basis for the ongoing Superfund cleanup in Libby, as well as at dozens of manufacturing facilities where the substance was processed.

Many industry officials, as well as EPA peer reviewers, have also said that the methodology the agency uses to assess LAA could also be used to assess other forms of asbestos.

In its 2011 draft of the assessment, EPA proposed a first-time noncancer reference concentration (RfC) -- the maximum amount of LAA the agency estimates can be inhaled daily over a lifetime without adverse noncancer health effects -- at 0.00001 fibers per cubic centimeter (f/cc). The background level of asbestos in United States soils is estimated to be 0.00005 f/cc.

EPA based its RfC on the presence of localized pleural thickening (LPT) and asbestosis, as observed in workers exposed to LAA in a processing plant in Marysville, OH. The agency describes LPT as growths "of fibrous tissue within the sack that surrounds the lung," and asbestosis as "an illness of progressive scarring of lung tissue."

But Grace's petition argues that LPT is not an adverse health effect, but merely a change indicating asbestos exposure. As such, LPT should not be the basis for EPA's RfC, which should be based on an adverse affect per EPA guidelines, the petition argues.

EPA science advisors, however, largely supported EPA's use of LPT and the data EPA selected to calculate the RfC. EPA's Science Advisory Board peer reviewed the draft assessment in 2012, and generally rebuffed industry criticism of LPT and agreed with the agency that it should maintain its use. But some panelists expressed concern about the stringency of the RfC, and pressed EPA to carefully review the draft in light of analyses of other types of asbestos fibers. Among other recommendations, the advisors urged EPA to review the RfC calculation and its basis, and consider studies of other worker cohorts besides the Marysville, OH studies to bolster the RfC.

Grace also questions EPA's modeling approaches for calculating its risk estimates, and its use of ". . .extremely small data sets, rendering the assessment incomplete and biased when calculating toxicity values . . ."

And Grace questions the utility of the draft IRIS assessment, arguing that its risk calculations will not be useful to the public and cleanup managers because the risk number is below naturally occurring background levels of LAA in soil. -- *Maria Hegstad*

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